DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 3rd Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-410
FAX: (612) 334-4134

August 9, 2006

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 06 - 32

Todd R. Meech
Owner
24615 County Road 12
Sebeka, Minnesota 56477

Dear Mr. Meech:

An investigation of your dairy operation located at Sebeka, Minnesota, was conducted by an investigator from the Minnesota Department of Agriculture, acting on behalf of the U.S. Food and Drug Administration (FDA), on April 27, 2006. This investigation confirmed that you offered animals for sale for slaughter as food that was adulterated under sections 402(a)(2)(C)(ii) [21 U.S.C. 342(a)(2)(C)(ii)] and 402(a)(4) [21 U.S.C. 342(a)(4)] of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused the new animal drugs penicillin G procaine, tylosin, oxytetracycline, and lincomycin to become adulterated within the meaning of section 501(a)(5) [21 U.S.C. 351(a)(5)] and unsafe under section 512 of the Act [21 U.S.C. 360b]. You can find the Act and its associated regulations on the Internet through links on the FDA web page at *www.fda.gov.*

On or about January 9, 2006, you consigned a dairy cow, identified with back tag 9287, for slaughter as food through [redacted]. On or about January 10, 2006, this animal was slaughtered at [redacted]. The United States Department of Agriculture Food Safety and Inspection Service (USDA/FSIS) analysis of tissue samples collected from that animal identified the presence of 13.05 ppm neomycin in kidney tissue.

On or about March 13, 2006, you consigned a dairy cow, identified with back tag 0081, for slaughter as food through [redacted]. On or about March 14, 2006, this animal was slaughtered at [redacted]. The USDA/FSIS analysis of tissue samples collected from that animal identified the presence of 14.61 ppm neomycin in kidney tissue.

A tolerance of 7.2 ppm has been established for residues of neomycin in kidney tissues of cattle as codified in Title 21, Code of Federal Regulations, 556.430 (21 CFR 556.430). The presence of this drug in kidney tissue from these animals in these amounts causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act [21 U.S.C. 342(a)(2)(C)(ii)].

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You lack an adequate system to ensure that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. For example, you failed to maintain treatment records, and you failed to maintain a system for identifying medicated animals at the time of purchase to ensure that the animal is withheld from slaughter for the appropriate period of time. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the Act [21 U.S.C. 342(a)(4)].

In addition, you adulterated penicillin G procaine, tylosin, oxytetracycline, and lincomycin within the meaning of section 501(a)(5) of the Act [21 U.S.C. 351(a)(5)] when you failed to use these drugs in conformance with their approved labeling. "Extralabel use," i.e., the actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling, is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship. The extralabel use of approved veterinary or human drugs must comply with sections 512(a)(4) and 512(a)(5) of the Act and 21 CFR 530. Our investigation found that your extralabel use of penicillin G procaine, tylosin, oxytetracycline, and lincomycin failed to comply with these requirements.

For example, you administered the penicillin G procaine without following the dosage level and dosage amount per injection site set forth in the approved labeling, and you did so without the supervision of a licensed veterinarian, in violation of 21 CFR 530.11(a). In addition, you administered tylosin, oxytetracycline, and lincomycin hydrochloride without following the animal class set forth in the approved labeling, and you did so without the supervision of a licensed veterinarian, in violation of 21 CFR 530.11(a). Because your extralabel use of these drugs was not in compliance with 21 CFR 530, your use caused the drugs to be unsafe under section 512(a) of the Act [21 U.S.C. 360b(a)] and your use caused them to be adulterated within the meaning of section 501(a)(5) of the Act [21 U.S.C. 351(a)(5)].

The above is not intended to be an all inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Brian D. Garthwaite, Ph.D., Compliance Officer, at the address located on the letterhead. If you have any questions about this letter, please contact Dr. Garthwaite at (612) 758-7132.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

BDG/ccl

xc: [redacted], D.V.M.

Dave Syverson
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, Minnesota 55107

Dr. Julie Cornett
USDA-FSIS
Technical Service Center
Landmark Center, Suite 300
1299 Farnam Street
Omaha, NE 68102